Compiled Draft for Additional Public Comment Adopt 17 Cal. Code of Regs. section 100070 to read:

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§ 100070. SCRO Committee Review and Notification.

3	(a) CIRM-funded research involving the procurement or use of human oocytes may not
4	commence without SCRO committee review and approval in writing. For such SCRO
5	committee review and approval, the member of the committee with expertise in assisted
6	reproduction shall be present. The designated SCRO committee may require that modification be
7	made to proposed research or documentation of compliance with the requirements of subdivision
8	(a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO
9	committee shall require the investigator to:
10	(1) Provide an acceptable scientific rationale for the need to use oocytes
11	including a justification for the number needed. If SCNT is proposed a justification for
12	SCNT shall be provided.
13	(2) Demonstrate experience, expertise or training in derivation or culture of
14	human or nonhuman stem cell lines.
15	(3) Provide documentation of compliance with any required review of the
16	proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC),
17	Institutional Bioethics Committee (IBC), or other mandated review.
18	(b) CIRM-funded research involving use of human embryos may not commence without
19	SCRO committee review and approval in writing. For such SCRO committee review and
20	approval, the member of the committee with expertise in assisted reproduction shall be present.
21	The designated SCRO committee may require that modification be made to proposed research or
22	documentation of compliance with the requirements of subdivision (b)(3) of this regulation as a
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1	Compiled Draft for Additional Public Comment condition of granting its approval. At a minimum, the SCRO committee shall require the
2	investigator to:
3	(1) Provide an acceptable scientific rationale for the need to use embryos
4	including a justification for the number needed.
5	(2) Demonstrate experience, expertise or training in derivation or culture of
6	human or nonhuman stem cell lines.
7	(3) Provide documentation of compliance with any required review of the
8	proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC),
9	Institutional Bioethics Committee (IBC), or other mandated review.
10	(c) CIRM-funded research with the aim to derive or create a covered stem cell line may
11	not commence without SCRO committee review and approval in writing. The designated SCRO
12	committee may require that modification be made to proposed research or documentation of
13	compliance with the requirements of subdivision (c)(4) of this regulation as a condition of
14	granting its approval. At a minimum, the SCRO committee shall require the investigator to:
15	(1) Provide an acceptable scientific rationale for the need to derive a covered
16	stem cell line.
17	(2) If SCNT is proposed as a route to generating human stem cell lines, a
18	justification for SCNT shall be provided.
19	(3) Demonstrate experience, expertise or training in derivation or culture of
20	human or nonhuman stem cell lines.
21	(4) Provide documentation of compliance with any required review of the
22	proposed research by an IRB, Institutional Bioethics Committee (IBC), or other
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1	Compiled Draft for Additional Public Comment mandated review.	
2	(5) Document how stem cell lines will be characterized, validated, stored, and	d distributed
3	to ensure that the confidentiality of the donor(s) is protected.(d) CIRM-funded purely	in vitro
4	research utilizing covered stem cell lines may not commence without written notification	tion to the
5	designated SCRO committee. At a minimum, the notification shall:	
6	(1) Provide assurance that all covered stem cell lines have been accept	<u>otably</u>
7	derived.	
8	(2) Provide documentation of compliance with any required review of	f the
9	proposed research by an IRB, IACUC, IBC, or other mandated review.	
10	(e) CIRM-funded research introducing covered stem cell lines into non-huma	an animals
11	or introducing neural-progenitor cells into the brain of non-human animals at any star	te of
12	embryonic, fetal, or postnatal development may not commence without SCRO comm	ittee review
13	and approval in writing. The designated SCRO committee may require that modification	tion be
14	made to proposed research or documentation of compliance with the requirements of	subdivision
15	(e)(3) of this regulation as a condition of granting its approval. The SCRO committee	e may
16	establish guidelines and procedures for expedited review of animal research so that re	eview by the
17	entire SCRO committee is not required. At a minimum, the SCRO committee shall re-	equire the
18	investigator to:	
19	(1) Provide an acceptable scientific for rationale introducing stem cel	ls into non-
20	human animals.	
21	(24) Provide assurance that all covered stem cell lines have been acce	<u>ptably</u>
22	derived.	
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1	(32) Evaluate the probable pattern and effects of differentiation and integration of
2	the human cells into the nonhuman animal tissues.
3	(43) Provide documentation of compliance with any required review of the
4	proposed research by an IRB, IACUC, IBC, or other mandated review.
5	(f) CIRM-funded research introducing stem cells from covered stem cell lines into a live
6	born human may not commence without SCRO committee review and approval in writing. The
7	designated SCRO committee may require that modification be made to proposed research or
8	documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a
9	condition of granting its approval. At a minimum, the SCRO committee shall require the
10	investigator to:
11	(1) Provide an acceptable scientific for rationale introducing stem cells into
12	<u>humans.</u>
13	(2) Provide assurance that all covered stem cell lines have been acceptably
14	derived.
15	(3) Evaluate the probable pattern and effects of differentiation and integration of
16	the human cells into the human or nonhuman animal tissues.
17	(4) Provide documentation of compliance with any required review of the
18	proposed research by an IRB, IACUC, IBC, or other mandated review.
19	(g) Investigators are entitled to reconsideration of a SCRO committee decision. Requests
20	must be made in writing and include a summary of the basis for the reconsideration.
21	Investigators are entitled to be present in order to provide information and responses during the
22	reconsideration. 5/11/06 4 Corrected 100070 Revised – Public Comment

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- 1 (h) SCRO committee approvals shall be reviewed no less frequently than once per year.
- 2 The renewal review shall confirm compliance with all applicable rules and regulations. The
- 3 SCRO committee may establish guidelines and procedures for expedited review of renewals so
- 4 that review by the entire SCRO committee is not required.
- Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
- 6 <u>Health and Safety Code.</u>
- 7 Reference: Sections 125290.40, 124290.55, Health and Safety Code.